

REMARKS

The specification was subject to objection alleging that a prior amendment directed to Page 8 of the specification could not be entered, purportedly being in the incorrect form with directions with an incorrect placement. Such amendment is no longer required.

Support for new claims 145-157, lies entirely in the 1997 application filed by Applicants. See for example, original claims 69-105, on page 13 last paragraph, a preferred heating of fixed tissue at a temperature of at least 80°C for a period of at least about 20 min. is mentioned. This is also inherent in the nature of the descriptive material. The pH ranges of about 1 to 11 and 5 to about 8 are specifically mentioned on pages 10 and 11. The amounts of surfactant paraffin removing agent, as well as tissue activating agent are described throughout the original specification including Pages 11-15. General support for claim 1 is also seen in specification, pages 6-10. Surfactants and detergents are discussed in numerous places, including pages 7-9. Weight percentage definitions are given e.g., on Page 12, Line 5 to Page 13, Line 10.

Tissue activating agents are described in many places, including page 9, Line 27 to Page 11, Line 5. Metal salts acting as tissue activating agents are discussed on page 11, Lines 24-30 and elsewhere in this 1997 specification. Support for claim 151 lies on page 7, second full paragraph. Support for amended claim 150 lies on Page 7, final full paragraph. Support for claim 151, lies in original claims 10-12 and on Page 3, last full paragraph, for example. Support for claim 154 lies on Page 11 and 12. Support for claim 155, lies on Page 12, first partial paragraph. The objection to the specification is obviated because the specific material requested to be entered is no longer needed to support any claim. The Office Action complains of a defective Declaration in that Applicant is not appropriately knowledgeable of the duty to disclose any appropriate information. Please note the accompanying Inventor's Declaration, appropriately modified.

All pending claims were rejected under 35 U.S.C. 112, second paragraph, because of an alleged lack of definition for percentage ingredients. As the present amendments remove said percentages, this point is no longer pertinent. Comment is made about traditional Markush-type language, and it is believed that the present claims more than adequately state the same. The new claims should be free of such objections.

Claims 17-21, 22, 27-35, 37, and 41-44 were rejected under 35 U.S.C. 102(b) over an immunopathology catalog produced by Applicant Cell Marque Corporation in view of the Kennedy patent (U.S. 5,856,289). This rejection is obviated because both specific written description for the present claims as well as enablement are clearly described in the 1997 application. Thus, the 1997 application is fully enabling to one of skill in the art. This enablement is supported by the accompanying Declaration under 37 C.F.R. 1.132 by Dr. Mike Lacey. The 1997 filing date is appropriate as a priority date for the preset application stemming from an intermediate CIP which added only non-essential information. Applicant provides herewith a 37 C.F.R. 1.131 Declaration by the inventors clearly establishing a date of invention prior to the March 1997 publication date of the Yorukoglu et al. reference. Once this reference is removed, there is no teaching whatsoever in Hazelbag et al., or any of the other references of an aqueous solution of a surfactant for the

deparaffinization and reactivation of fixed tissue for immunostaining. Hazelbag et al. clearly uses traditional methods of xylene dewaxing for all paraffin fixed slides. This is exemplified in the second column, final paragraph of Page 430. Not only does Hazelbag teach only traditional methods, it teaches multiple steps for obtaining the immunological activation of the present invention. There are no single step methods for such immunological reactivation in any of the other references either. Hazelbag et al., while mentioning heating of detergent solutions, only applies this to xylene-dewaxed tissues.

Applicant also provides herewith (see Appendix B) a set of seven laudatory comments by users of the present methodology and compositions. This is to illustrate secondary considerations relating to non-obviousness, as does the 1.132 declaration of Dr. Mike Lacey.

The Patent Office's attention is brought the four items supplied herewith:


1. An Inventor's Declaration with the appropriate serial number of the current applications;
2. An Inventor's Declaration under 37 C.F.R. 1.131 establishing an early invention date.
3. A set of comments sent by Cell Marque customers.
4. A declaration under § 37 CFR 1.132 by Dr. Mike Lacey attesting to the inventivity of the present invention.

Attached hereto is a marked-up version of the changes made to the specification by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

Should the Examiner have any questions in this matter, a telephone call to the Applicant's undersigned representative at his desk phone of 210-228-2408 is earnestly requested.

Should any fees greater than the enclosed check be due, the Commissioner is authorized to deduct such fees from deposit account number 07-2400/Dkt P6335.01CPA.

Respectfully submitted,

By 
Daniel S. Hodgins, Ph.D Reg. No. 81,026

JACKSON WALKER L.L.P.

112 E. Pecan Street, Suite 2100

San Antonio, TX 78205

Tel: (210) 978-7700

Fax: (210) 978-7790

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specifications:

On Page 11 in the penultimate line of the third full paragraph delete "dehydrate" and substitute -- dihydrate-- therefor:

C 1
-- In a preferred embodiment, the composition is an aqueous solution which includes (a) up to about 25 percent by volume of SIMPLE GREEN and (b) up to about 10 percent by weight of citric acid and alkaline citrate salts. In a more preferred embodiment the composition is an aqueous solution which includes (a) about 1.85 percent by volume of SIMPLE GREEN, (b) about 0.3 percent by weight of trisodium citrate [dehydrate] ^{dihydrate} ~~anhydrate~~ and (c) sufficient concentrated hydrochloric acid to obtain a pH of about 5.96 to 6.04-- ^

On Page 4 at the end of the first sentence of the first full paragraph add the followings:

-- In another embodiment the composition preferably includes an aqueous solution of SIMPLE GREEN. Simple Green has been described in U.S. Patent No. 5,856,289 as: by weight about 5.8% ethylene glycol monobutyl ether, about 3.75% nonylphenol ethoxyate, about 1.5% tetrapotassium pyrophosphate and about 88.95% water. SIMPLE GREEN is a non-toxic, biodegradable, environmentally safe detergent concentrate which may provide a mixture of emulsifiers. The composition may include a buffering agent. The pH of the solution is preferably adjusted to lie between 5 and 10 by addition of an acid or a base. The composition preferably substantially simultaneously: (i) removes the embedding medium from the tissue; (ii) improves immunohistochemical staining of the tissue in comparison to tissue that has not been contacted with the composition; (iii) substantially hydrates the tissue.--

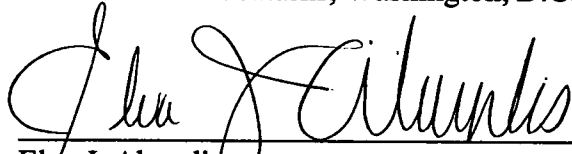
In the Claims:

Cancel all prior claims, including mis-numbered claims 17-44 and add claims 145-157.

CERTIFICATE OF MAILING

Express Mail Label No. EV 052647912 US Dated: April 19, 2002.

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited on this date with the United States Postal Service in an Express Mail envelope addressed to the "Commissioner of Patents and Trademarks, Washington, D.C. 20231."



Elya J. Abundis

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